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10/622,437	07/18/2003	Thomas J. Fogarty	FGRTNZ00200	4971

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/622,437
Filing Date: July 18, 2003
Appellant(s): FOGARTY ET AL.

David Levine
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 28, 2009 appealing from the Office action mailed October 28, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

The examiner notes the related appeals listed in the Appeal Brief are moot since they are no longer pending.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 39-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berenstein et al. (US 6,458,119, hereinafter "Berenstein") in view of Ritchart et al. (US 4,994,069, hereinafter "Ritchart"). Berenstein discloses the invention substantially as claimed including a method of filling an aneurysm, or abnormal void within the body, by placing a catheter into the aneurysm and injecting a vaso-occlusive coil into the aneurysm. The coil consists of chain links as shown in Figs 6A-6C, which are the claimed first and second space occupying elements, wherein the space occupying elements are rotatably attached. The coil additionally includes polymeric filaments (602 or 604) of a thrombogenic material, to provide a ready substrate for clot formation in the interior region of the aneurysm, and thus may be considered a clot binding agent.

However, Berenstein does not disclose a coating comprising a binding agent, wherein the binding agent reduces the flexibility of the space-occupying device. Ritchart discloses a similar space occupying device for filling an aneurysm, or abnormal void within the body, wherein the device includes a coating comprising a binding agent (36) for reducing the flexibility of the device (col 8, ll 39-51). Ritchart teaches the binding agent is a rigid water soluble material such that the coating can be applied to the interior or exterior of the device and dehydrated to form a rigid shell within or about the device (col 5, ln 62 - col 6, ln 5). Upon contact with fluid, which acts as a softening

agent, within the catheter or at the delivery site, the coating dissolves and the device may regain its flexible nature. Thus, the device can be easily threaded into the catheter in its rigidified form and regain its flexible nature at deployment to simplify the delivery of the device (col 8, ll 39-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Berenstein such that the space-occupying device that is passed through the catheter additionally included a coating, wherein the coating comprises a binding agent which reduces the flexibility of the space-occupying device as taught by Ritchart in order to more easily pass the space-occupying device through the catheter. Furthermore, it would have been obvious to add the method step of exposing the device to a softening agent to dissolve the rigidifying coating, thus allowing the device to regain its flexible nature at the time of deployment. This modification would simplify the delivery process.

(10) Response to Argument

Appellant argues Berenstein's fibers (602) are used for clot formation, and do not reduce the flexibility of the space-occupying device. The examiner agrees the fibers (602) are designed for clot formation, and while they are capable of minimally reducing the flexibility of the space-occupying device as arranged in Fig 6B compared to the arrangement in Fig 6C, they are not designed for significantly reducing the flexibility of the space occupying device. However, the examiner's intent was not to interpret the fibers (602) as the claimed coating comprising the binding agent designed to reduce the flexibility of the space occupying device. Rather, the fibers are a binding agent in the sense that they help induce clot formation and help bind a thrombus within the

aneurysm. Berenstein was modified in view of Ritchart as shown above to provide a coating comprising a binding agent to act as a stiffening agent disposed over both the chain (600) comprising the first and second space occupying devices and the fibers (602).

Appellant additionally argues that one of two situations would exist in the combination of Berenstein and Ritchart: "(1) the water soluble material 36 would not be activated (i.e., not dehydrated to form a rigid shell) in the delivery catheter, thereby providing no effect to keep the device relatively straight during delivery or (2) the water-soluble material would be active in the catheter pre-deployment and thereby reduce the ability of the device to navigate the naturally tortuous configuration of the deployed catheter and the available anatomical void into which it is being deployed." Regarding the first situation, Ritchart clearly teaches the water soluble material would be activated initially in the delivery catheter and thus the coating would simplify the delivery process by keeping the device relatively straight while being passed through the catheter. Regarding the second situation, when the binding agent is exposed to fluid, or a softening agent, the stiffening effect of the coating is reversed and thus the device may regain its highly flexible nature as it is delivered to the target location. Thus, the coating simplifies the delivery process by providing column strength to assist in loading the device within the catheter and dissolving when it is desirable for the device to be flexible to navigate the tortuous vessel and/or fit within the aneurysm.

Appellant additionally argues applying the water-soluble coating of Ritchart would not change the inherent solubility properties of the fibers (602) in Berenstein. The

examiner agrees with the appellant's remarks. However, the Examiner notes the intent is not to modify the fibers such that they are water soluble, but rather to add the water soluble coating of Ritchart to the entire device of Berenstein, including the fibers and first and second space occupying devices. Thus the coating provides the desired structural stiffness for delivery, but dissolves when it is no longer necessary and it is desirable to have a flexible space occupying device that may be deployed to the target location. The fibers do not dissolve when they contact fluid such that they may induce clot formation within the aneurysm.

Appellant additionally argues the purpose of the binding agent of appellant's device is not to dissolve in water, but to reduce the flexibility of the space-occupying device. First, it is to be noted that the appellant's claims do not recite the binding agent being insoluble in water. The purpose of the binding agent as taught by Ritchart is to reduce the flexibility of the space-occupying device (col 8, ll 39-51). However, when it is no longer desirable for the space-occupying device to have a reduced flexibility, it is necessary that the binding agent dissolve in water. Thus, the binding agent dissolving in water reads on the limitations of the flexibility of the space-occupying device increasing when the binding agent is exposed to a softening agent (see for example claim 40).

Finally, the appellant argues it would not have been obvious to modify Berenstein in view of Ritchart because a binding agent in the form of fibers would have improved and faster dissolvability compared to a binding agent in the form of a coating. Again it appears the appellant misunderstood the rejection. The combination of Berenstein with

Ritchart was not replacing the fibers (602) with a coating or making the fibers dissolvable in water. Rather, the combination provided the coating of Ritchart to the entire device of Berenstein in order to rigidify the device.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Katherine Dowe

/K. M. D./

Examiner, Art Unit 3734

Conferees:

Todd Manahan

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